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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/386,266**

Applicant(s)  
**Brayden**

Examiner  
**S. Devi, Ph.D.**

Group Art Unit  
**1645**



☒ Responsive to communication(s) filed on 02/29/2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-34 ~~is~~ are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-34 are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some\* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

**Restriction/Election**

- 1) Claims 1-34 are under prosecution.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-6 and 15-20, drawn to a vaccine formulation comprising microparticles of an antigen entrapped by a biodegradable polymer and a method of inducing a T<sub>H</sub>1 polarised immune response to an antigen by administering the same, classified in class 424, subclass 9.322.
  - II. Claims 7-12 and 21-26, drawn to a vaccine formulation comprising nanoparticles of an antigen entrapped by a biodegradable polymer and a method of inducing a T<sub>H</sub>2 polarised immune response by administering the same, classified in class 424, subclass 184.1.
  - III. Claims 13 and 14, drawn to a method of inducing a combined T<sub>H</sub>1 and T<sub>H</sub>2 immune response to an antigen by administering the antigen entrapped by a biodegradable polymer to form microparticles and nanoparticles, classified in class 514, subclass 885.
  - IV. Claims 27-34, drawn to a method of providing protective immunity against *B. pertussis* by administering microparticles or nanoparticles of a *B. pertussis* antigen entrapped by a biodegradable polymer, classified in class 424, subclass 254.1.
- 4) Inventions I through IV are distinct from each other. The product and the method of invention I and invention II are related as product and process of using the product and hence are

grouped together. Inventions I, II, III and IV are directed to methods which differ from one another in method steps, parameters and/or the compositions used and the ultimate goals, i.e., the type of immunity, accomplished.

5) Inventions III and each of inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP 806.05(c)). In the instant case, the combination as claimed, representing a method of inducing a combined  $T_H1$  and  $T_H2$  immune response to an antigen, does not require the particulars of the subcombination as claimed for patentability, because the method claimed is an individually distinct method. And the subcombination methods of inventions I and II are individually distinct methods having their own separate utility or practice independent of the combination method.

6) Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classification/subclassification and divergent subject matter, restriction for examination purposes as indicated is proper.

7) The instant application contains claims directed to patentably distinct species of the claimed invention. Election to one of the following species of *B. pertussis* antigen, which are distinct from one another in their structure, properties and immunologic specificity, is required in claims 30 and 34:

- a) Pertussis toxin (Ptd);
- b) Filamentous hemagglutinin (FHA);
- c) Pertactin, and
- d) Fimbriae.

Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

8) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

Serial Number 09/386.266

Art Unit: 1645

9) Should Applicants traverse on the ground that the species are not patentably distinct. Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD  
S. Devi  
Patent Examiner  
July 2000



# RESTRICTION ELECTION FACSIMILE TRANSMISSION

DATE:

FROM/ATTORNEY:

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